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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/606,808 06/28/00 LARKINS

J DEKA: 264

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HM22/1002

EXAMINER

BENZION, G

ART UNIT	PAPER NUMBER
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1638  
DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/606,808	Applicant(s) LARKINS ET AL.
	Examiner Gary Benzion, Ph.D.	Art Unit 1638
	-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --	
<b>Period for Reply</b>		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM <b>THE MAILING DATE OF THIS COMMUNICATION.</b>		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
1) <input type="checkbox"/> Responsive to communication(s) filed on <u>08 January 2001</u> . 2a) <input type="checkbox"/> This action is <b>FINAL</b> .      2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-39</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input checked="" type="checkbox"/> Claim(s) <u>1-39</u> is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.		

*Status of the Application*

Claims 1-39 are pending.

*Detailed Action*

The following is a quotation of the first paragraph of 35 § U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-39 are incomplete, and therefore indefinite, by the recitation of "and having been deposited under ATCC accession No. \_\_\_\_" as set forth in claims 1, 4, 7, 8, 10, 13, 18, 19 and 29. In the interest of compact prosecution, and in the event the instant application matures into a US Patent, correction of the deficiency may be deferred. See 37 CFR 1.809 and MPEP 2400.

Claims 1-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The designation LIZL5 is both vague and indefinite by failing to point out with particularly the metes and bounds of the claimed subject matter which applicant regards as the invention. The denomination LIZL5 is not known in the art and as such carries no art recognized limitation as to the specific characteristics, or those deemed essential, that are associated with the denomination LIZL5. For example, the maize inbred name associated with this line, as described in the specification, appears arbitrary and could be changed to an alternative denomination or the specific characteristics associated therein could be modified, as there is no written description of the maize plant that encompasses all of its traits. Similarly, reference to a plant or cell consisting of (or having) an RFLP and/or isozyme profiles, or a plant possessing said profile(s) are considered both vague and indefinite by failing to point out with particularly the metes and bounds of the claimed subject matter which applicant regards as the invention,

as maize *per se* is not universally classified by such nomenclature. In any event the ability of a person having skill in the art to determine the metes and bounds of the claimed subject matter would be limited. See *In re Hammack*, 427 F.2d. 1378, 166 USPQ 204, 208 (CCPA 1970).

Claims 1-39 are rejected 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that seed of inbred LIZL5 is required to practice the claimed invention. As such said seed must be readily available, or obtainable, by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the seed capable of reproducing the claimed plant.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. Further, to be considered adequate a deposit should consist of at least 2,500 seeds of each claimed embodiment. In instances where the claimed invention consists of sexually unstable material a deposit of the parental material is required if the parental material is considered sexually stable. In lieu of this requirement regenerable clonal material may be deposited to satisfy the specific enablement where the above material cannot be provided. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the effective life of the patent, whichever is longer;

- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable;

At page 27 of the specification applicants indicate their intention to prefect a deposit of the instant inbred line, however, the date and accession numbers are blank. A complete response to this rejection would include a statement of applicants' intention with regard to the deposit statement at page 27.

Furthermore, the recitation in which claims are drawn to the named inbred, in the absence of linkage to the deposit accession number, is similarly incomplete, indefinite and not enabling. Such claims should be amended to indicate the deposit accession number, or have dependency to claims which recite the enabling deposit number, to correct the deficiency under 35 U.S.C. § 112. An acceptable response at this time would be Applicant's statement of intention to deposit the material upon the indication of allowable subject matter, and to amend the specification as required under 37 CFR 1.801-1.809 and MPEP 2400.

Claims 8, 9, 10-13 and 14-17 are rejected 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclose the physiological and morphological characteristics of inbred corn line LIZL5 and, in the event of an acceptable deposit of seed capable of producing this inbred line, enable the person having skill in the art the ability to make and use the invention. The specification does not describe other plants having all the physiological and morphological characteristics of inbred corn line LIZL5, nor does it enable the person having skill in the art to make a line having all its physiological and morphological traits as the parental material is propriety, and the selection criteria employed to make LIZL5 is not disclosed, nor are RFLP or isozyme profiles correlated to the physiological or morphological characteristics. Clearly the claimed invention is broader than that which is enabled by the deposit of LIZL5 and as such is not enabled by said deposit. In this regard the decision in *Ex parte Tanksley* (BdPatApp&Int) 37 USPQ2d 1382, is noted. In *Tanksley*, claims to DNA clones which on first analysis appeared to be enabled by a deposit, were later found to be indefinite based on statements made in the specification as to what applicants believed to be DNA equivalents, and thus broader than that warranted by the deposit of material consisting of distinct DNA sequences. In the instant case Applicant's specific

contribution is limited to that which will be deposited and its equivalents, to the extent that the claims under question are interpreted to consist of the deposited inbred line LIZL5 and plants and seed which are demonstrated to be LIZL5 whether presented with or without the trivial name. Similarly, plant produced by tissue culture or those possessing the RFLP and/or isozyme pattern described in the specification which are not derived from the deposit of LIZL5 are considered limited to those plants which are identical to the deposited material. That is, the claims may be considered to cover the seeds, plants and hybrids made by the use of LIZL5 that have not been deposited, so long as said seeds, plants and hybrids have all the physiological and morphological characteristics of LIZL5 which is represented by the deposited sample. Alternatively, the claims may be interpreted to include trivial modification of enabled seed, plants and hybrids of LIZL5 in which the corn retains all the physiological and morphological characteristics of inbred corn line LIZL5 , its parts, and hybrids which are not broader than that found enabled by the deposit. As currently claimed, the specification does not teach the metes and bounds of any modification of the corn and as such the claimed invention is considered broader than that which is enabled by the deposits of seed of LIZL5 .

Claims 10-13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to a plant possessing all of the physiological and morphological characteristics of inbred line LIZL5 . See MPEP 706.03(n) and 706.03(z).

The specification discloses the art recognition of the tissue culture and regeneration of plants of many, if not most, maize inbred lines through conventional *in vitro* means. Although the specification describes the phenotypic characteristics of inbred LIZL5 produced from seed, it is silent as to the phenotypic characterization of the tissue culture and of plants produced through tissue culture regeneration. Such plants would be recognized by a person having skill in the art as not possessing the genotype of the inbred explant as was noted by Phillips et al. (p358, section 5-2);

... the likelihood appears to be quite low that a corn plant regenerated from culture is identical in genotype to the donor tissue.

In view of this teaching and in the absence of evidence of the degree and type of genotypic variation that will manifested in the phenotypic characteristics of regenerants, the specification would appear to be inadequate to describe or enable a plant produced from the tissue culture of the instant inbred. Such a plant, in view of the statement by Phillips et al., could not contain the exact genotype of the parent plant. Changes in essential genes would result in a plant possessing some, of but certainty not

all, of the features of the claimed plant and would be beyond the scope of the person having skill in the art to predict what specific changes would result, however, many of those changes or mutations would be silent and thus not expressed producing a plant that possessed all of the physiological and morphological characteristics of the claimed inbred line, but varying by silent or subtle changes in the genotype of the claimed plant. Accordingly the claimed invention must be limited to regenerant plants that possessed all the physiological and morphological characteristics of the instant inbred, regardless of any cryptic or silent variation found in the genotype of the plant.

*Prior art.*

Claims 1-39 are considered free of the prior art. Claims 1-28 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. § 112 set forth in this Office Action.

*Summary*

No claim is allowed.

*Inquires*

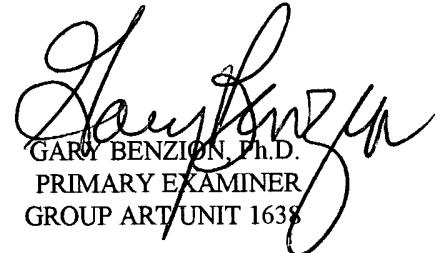
Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D. whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703)-308-4310. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Benzion  
9/30/01

Serial No. 09/606,808  
Art Unit 1638

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GARY BENZION, Ph.D.  
PRIMARY EXAMINER  
GROUP ART UNIT 1638